Amendments to the Claims

The following listing of claims replaces all prior listings and versions of claims in this application.

1. (Currently Amended) A formulation for transdermal or transmucosal administration of an active agent, the formulation comprising: at least one active agent, provided that when the active agent is ~~an~~ estrogen, a progestin is not present in the formulation, and when the active agent is ~~or~~ progestin, ~~a therapeutically effective amount of a progestin or~~ estrogen~~,~~ ~~respectively,~~ is not present in the formulation; and a delivery vehicle comprising a C_2 to C_4 alkanol, a polyalcohol, and a permeation enhancer of monoalkyl ether of diethylene glycol present in an amount sufficient to provide permeation enhancement of the active agent through dermal or mucosal surfaces; wherein the formulation is substantially free of long-chain fatty alcohols, long-chain fatty acids, and long-chain fatty esters in order to avoid undesirable odor and irritation effects caused by such compounds during use of the formulation.

2. (Original) The formulation of claim 1, wherein the polyalcohol is present in an amount between about 1% and 30% of the vehicle; and the permeation enhancer is present in an amount of between about 0.2% and 25% of the vehicle.

3. (Original) The formulation of claim 1, wherein the active agent is testosterone present in an amount between about 0.05% to 10% of the formulation; the alkanol is present in an amount between about 20 to 65% of the formulation; the polyalcohol is propylene glycol present in an amount between about 1% to 15% of the formulation; the permeation enhancer is diethylene glycol monoethyl ether present in an amount between about 1% to 15% of the formulation, and further wherein the formulation comprises a gelling agent present in an amount of between 0.05% to about 4% of the formulation, a neutralizing agent present in an amount between about 0.05% and 1% of the formulation, and water present in an amount between about 20% to 65% of the formulation.

4. (Original) The formulation of claim 3, wherein the formulation further includes a sequestering agent.

5. (Original) The formulation of claim 1, wherein the polyalcohol and permeation enhancer are present in a weight ratio of 2:1 to 1:1.

6. (Original) The formulation of claim 1, wherein the polyalcohol and permeation enhancer are present in a weight ratio of 1.25:1 to 1.2:1.

7. (Original) The formulation of claim 1, wherein the alkanol is present in an amount of 5 to 75% by weight of the vehicle.

8. (Original) The formulation of claim 1, wherein the alkanol is selected from the group consisting of ethanol, isopropanol and n-propanol.

9. (Original) The formulation of claim 1, wherein the polyalcohol is polypropylene glycol.

10. (Original) The formulation of claim 1 wherein the active agent is selected from the group including androgens, estrogens, or progestogens or any combination thereof.

11. (Original) The formulation of claim 1, wherein the active agent is selected from the group consisting of androgens, anti-androgens, estrogens, anti-estrogens, progestogens, anti-progestogens, adrenergic agonists, analgesics, sedatives, amides, arylpiperazines, nerve agents, antineoplastics, anti-inflammatory agents, anticholinergics, anticonvulsants, antidepressants, antiepileptics, antihistaminics, antihypertensives, muscle relaxants, diuretics, bronchodilators, and glucocorticoids.

12. (Original) The formulation of claim 1, wherein the at least one active agent is in combination with a secondary active agent for concurrent administration.

13. (Original) The formulation of claim 12, wherein the at least one or secondary active agent is a combination of methyltestosterone and esterified estrogen.

14. (Original) The formulation of claim 12, wherein the at least one or secondary active agent is a combination of testosterone and nandrolone decanoate.

15. (Original) The formulation of claim 12, wherein the at least one or secondary active agent is a combination of testosterone and estradiol.

16. (Original) The formulation of claim 1, wherein the formulation further comprises at least one of a gelling agent, neutralizing agent, sequestering agent, buffering agent, moisturizing agent, humectant, surfactant, antioxidant, emollient, or buffer.

17. (Original) The formulation of claim 16, wherein the gelling agent is selected from the group consisting of carbomer, carboxyethylene, polyacrylic acid, cellulose derivatives, ethylcellulose, hydroxypropylmethylcellulose, ethylhydrooxyethylcellulose, carboxymethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, natural gums, arabic, xanthan, guar gums, alginates, polyvinylpyrrolidone derivatives, polyoxyethylene polyoxypropylene copolymers, chitosan, polyvinyl alcohol, pectin, and veegum.

18. (Original) The formulation of claim 16, wherein the buffering agent is selected from the group consisting of carbonate buffers, citrate buffers, phosphate buffers, acetate buffers, hydrochloric acid, lactic acid, tartric acid, diethylamine, triethylamine, diisopropylamine, tetrahydroxypropylethylendiamine, and aminomethylamine.

19. (Original) The formulation of claim 16, wherein the sequestering agent is edetic acid.

20. (Original) The formulation of claim 1 wherein the formulation is in the form of a gel, lotion, cream, spray, aerosol, ointment, emulsion, suspension, liposomal system, lacquer, patch, bandage, or occlusive dressing.

21. (Currently Amended) A formulation for transdermal or transmucosal administration of an active agent, the formulation comprising: at least one active agent, provided that when the active agent is ~~an~~ estrogen, a progestin is not present in the formulation, and when the active agent is ~~or~~ progestin, ~~a therapeutically effective amount of a progestin or~~ estrogen~~, respectively,~~ is not present in the formulation; and a delivery vehicle comprising a C_2 to C_4 alkanol, a polyalcohol, and a permeation enhancer of monoalkyl ether of diethylene glycol to provide permeation enhancement of the active agent through dermal or mucosal surfaces, wherein the polyalcohol is propylene glycol and is present in an amount between about 1% and 30% of the vehicle, the permeation enhancer is diethylene glycol monoethyl ether and is present in an amount of between about 0.2% and 25% of the vehicle, the alkanol is ethanol and is present in an amount of 5 to 75% by weight of the vehicle wherein the formulation is substantially free of long-chain fatty alcohols, long-chain fatty acids, and long-chain fatty in order to avoid undesirable odor and irritation effects caused by such compounds during use of the formulation.

22. (Original) The formulation of claim 21, wherein the polyalcohol and permeation enhancer are present in a weight ratio of 2:1 to 1:1.

23. (Original) The formulation of claim 1 wherein the formulation comprises at least one of a gelling agent, neutralizing agent, sequestering agent, buffering agent, moisturizing agent, humectant, surfactant, antioxidant, emollient, or buffer and is in the form of a gel, lotion, cream, spray, aerosol, ointment, emulsion, suspension, liposomal system, lacquer, patch,

bandage, or occlusive dressing.

24. (Original) A formulation for epithelial administration of an active agent, the formulation comprising: at least one active agent comprising an androgen; and a delivery vehicle comprising a C_2 to C_4 alkanol, a polyalcohol, and a permeation enhancer of monoalkyl ether of diethylene glycol present in an amount sufficient to provide permeation enhancement of the active agent through epidermal surfaces; wherein the formulation is substantially free of long-chain fatty alcohols, long-chain fatty acids, and long-chain fatty esters in order to avoid undesirable odor and irritation effects caused by such compounds during use of the formulation.

25. (Original) The formulation of claim 24, wherein the alkanol is ethanol, the polyalcohol is propylene glycol, and the permeation enhancer is monoethyl ether of diethylene glycol.

26. (Original) The formulation of claim 24, wherein the formulation is in the form of a gel.

27. (New) The formulation of claim 24, wherein the active agent is a combination of testosterone with estrogen or progestin.

28. (New) The formulation of claim 1, wherein the active agent is estrogen or progestin.